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Atty. Dkt. No. 064189-0604

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Heinz-Josef LENZ, et al.
Title: POLYMORPHISMS FOR
PREDICTING DISEASE AND
TREATMENT OUTCOME
Appl. No.: 10/522,664
Filing Date: July 31, 2003
Examiner: Unassigned
Art Unit: Unassigned

<p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p>Esther Lily C. Esguerra (Printed Name)</p> <p><i>[Signature]</i> (Signature)</p> <p>January 11, 2006 (Date of Deposit)</p>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Applicants also bring to the Office's attention the following related applications: U.S. Patent Application Serial Nos.: 11/173,889, filed July 1, 2005 and 09/715,764, filed November 15, 2005.

The Commissioner is hereby authorized to charge any fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872.

Respectfully submitted,

Date: January 11, 2006

By Antoinette F. Konski

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

Date Submitted: January 11, 2006

Complete if Known

Application Number	10/522,664
Filing Date	July 31, 2003
First Named Inventor	Heinz-Josef Lenz
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	064189-0604

Sheet	1	of	2
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[illegible][illegible]

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: January 11, 2006 (use as many sheets as necessary)				Complete if Known	
				Application Number	10/522,664
				Filing Date	July 31, 2003
				First Named Inventor	Heinz-Josef Lenz
				Group Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	064189-0604
Sheet	2	of	2		

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	3	WO	04/037852	A2	University of Medicine and Dentistry of New Jersey; University of Southern California	May 6, 2004		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	4	IACOPETTA, B. et al. "A Polymorphism in the Enhancer Region of the Thymidylate Synthase Promoter Influences the Survival of Colorectal Cancer Patients Treated with 5-Fluorouracil" <i>British Journal of Cancer, London, GB</i> (September 14, 2001) 85(6):827-830	
	5	LENZ, HEINZ-JOSEF et al. "A 6 base-pair deletion in the 3' UTR of the thymidylate synthase (TS) gene predicts TS mRNA expression in colorectal tumors: A possible candidate gene for colorectal cancer risk" <i>Proceedings of the American Association for Cancer Research Annual Meeting</i> (March 2002) 43:660	
	6	PARK, DAVID J. et al. "Thymidylate synthase gene polymorphism predicts response to capecitabine in advanced colorectal cancer" <i>International Journal of Colorectal Disease</i> (January 2002) 17(1):46-49	
	7	PULLARKAT, S. et al. "Thymidylate Synthase Gene Polymorphism Determines Response and Toxicity of 5-FU Chemotherapy" <i>Pharmacogenomics Journal</i> (2001) 1(1):65-70	
	8	SHIROTA, Y. et al. "ERCC1 and Thymidylate Synthase mRNA Levels Predict Survival for Colorectal Cancer Patients Receiving Combination Oxaliplatin and Fluorouracil Chemotherapy" <i>Journal of clinical Oncology</i> (December 1, 2001) 19(23):4298-4304	
	9	Ulrich et al. "Searching Expressed Sequence Tag Databases: Discovery and Confirmation of a Common Polymorphism in the <i>Thymidylate Synthase</i> Gene" <i>Cancer Epidemiology, Biomarkers & Prevention</i> (2000) 9:1381-1385	
	10	Villafranca et al. "Polymorphisms of the Repeated sequences in the Enhancer Region of the Thymidylate Synthase Gene Promoter May Predict Downstaging After Preoperative Chemoradiation in Rectal Cancer" (2001) <i>Journal of Clinical Oncology</i> 19(6):1779-1786	
	11	European Search Report for EP 03 77 2163 dated October 4, 2005	

Examiner Signature	Date Considered	
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